

## **REMARKS**

Reconsideration and withdrawal of the rejections of this application and consideration and entry of this paper are respectfully requested in view of the herein amendment and remarks, which place the application in condition for allowance.

Applicants thank the Examiner for indicating that the rejections under 35 U.S.C. § 112, first and second paragraphs, were withdrawn in part.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 11-13, 16-19, and 34-37 are currently under consideration. Claims 11 and 34-37 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

The amendment to claim 11 is to clarify the claimed cells. Support can be found throughout the specification as originally filed, for example, on page 3, lines 15-26, in the paragraph bridging pages 3 and 4, and in Examples 1 and 3. The amendment to claims 34 and 36 is to perfect antecedent basis. The amendment to claims 35 and 37 is to clarify the relationship of the claimed cells with the deposited cell lines. Support can be found, for instance, in the specification in the paragraph bridging pages 3 and 4. No new matter is added.

It is submitted that the claims herewith are patentably distinct over the prior art, and these claims are in full compliance with the requirements of 35 U.S.C. § 112. The amendments to the claims presented herein are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply to clarify the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that these amendments should not give rise to any estoppel, as they are not narrowing amendments.

### **II. DOUBLE PATENTING REJECTION IS OVERCOME**

Claims 12 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 11, 15-17, and 19 of copending U.S. application Serial No. 11/031,417 (Applicants presume that the Office Action erred, and that claims 11, 15-17, and 19 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as allegedly being unpatentable over claims 12 and 14 of copending U.S. application Serial No. 11/031,417).

While Applicants disagree with the double patenting rejection, in order to expedite prosecution, Applicants are concurrently filing a Terminal Disclaimer to copending U.S. application Serial No. 11/031,417. Accordingly, Applicants request reconsideration and withdrawal of the double patenting rejection.

### **III. THE REJECTIONS UNDER 35 U.S.C. § 112 ARE OVERCOME**

#### **Written Description**

Claims 11-13, 16-19, and 34-37 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. This rejection is respectfully traversed.

The Office Action contended that, with the exception of the cell line TDF-2A, TDF-2A bcl-2, TCF 4.10 and TCF bcl-2, the skilled artisan cannot envision the chemical structure of the encompassed polynucleotides and/or proteins. The Office Action further alleged that there exists no correlation between the structure and the claimed function in light of the difficulty in obtaining immortalized cells and the propensity of SV40 T+t to lead to cell transformation.

While Applicants disagree with the Office Action's allegations, in the interest of advancing prosecution, instant claim 11 is herein directed to untransformed, immortalized, avian cell wherein the genome of the cell comprises a nucleic acid molecule encoding SV40 T+t, wherein the cell contains and expresses a nucleic acid molecule encoding an antiapoptotic protein, and wherein the cell is of cell line TDF-2A or is derived therefrom, or is of cell line TCF-4.10 or is derived therefrom. Therefore, instant claim 11, as well as instant claims 12, 13, 16-19, and 34-37 that depend therefrom, complies with the written description requirement. As discussed above, the claimed cell is substantially described on page 3, lines 15-26 and in the paragraph bridging pages 3 and 4, and a demonstration in preparing the claimed cell is provided in Examples 1 and 3-5. Moreover, the Office Action admitted that cell lines TDF-2A and TCF-4.10 meet the written description requirement (*see, e.g.*, Office Action, page 5).

Accordingly, Applicants request reconsideration and withdrawal the rejection.

### **Enablement**

Claims 11-13, 16-19, 34, and 36 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. This rejection is respectfully traversed.

The Office Action contended that, since avian cells are difficult to immortalize and the use of SV40 T+t leads to transformation in cells, the skilled artisan would not be able to produce an avian cell with the claimed genotypic and phenotypic characteristics without undue experimentation.

Applicants respectfully disagree with the Office Action's allegations; however, in order to expedite prosecution, instant claim 11 herein recites "[u]ntransformed, immortalized, avian cell wherein the genome of the cell comprises a nucleic acid molecule encoding SV40 T+t, wherein the cell contains and expresses a nucleic acid molecule encoding an antiapoptotic protein, and wherein the cell is of cell line TDF-2A or is derived therefrom, or is of cell line TCF-4.10 or is derived therefrom." With this in consideration, Applicants assert that instant claim 11, as well as claims 12, 13, 16-19, 34, and 36 that depend therefrom, comply with the enablement requirement. As discussed, the specification provides ample guidance and direction for the claimed invention, such as on page 3, lines 15-26 and in the paragraph bridging pages 3 and 4, and working examples demonstrate how to prepare the claimed cell, such as in Examples 1 and 3-5. Furthermore, the Office Action conceded that the specification is enabling for the immortalized and untransformed avian cell lines TDF-2A, TDF-2A bcl-2, TCF-4.10, and TCF-4.10 bcl-2 (*see, e.g.*, Office Action, page 7).

Accordingly, Applicants request reconsideration and withdrawal the rejection.

### **Indefiniteness**

Claim 37 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Office Action contended that the phrase "derived from the cell line TCF-4.10 bcl-2" renders the claim 37 vague. Claims 35 and 37 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. According to the Office Action, the phrase "progeny of the cell line . . ." is vague and indefinite as to what constitutes "progeny." These rejections are traversed and will be addressed collectively.

In response, Applicants draw attention to the instant claims, wherein claims 35 and 37 indicate that the claimed cell is of the recited cell line or is "derived therefrom," thereby further

clarifying the claimed cells. Applicants remind that they can be their own lexicographers (*see e.g.*, MPEP Section 2173.01), and that the skilled artisan would understand the term “derived” especially in light of the specification. In particular the specification states the following:

The invention naturally covers the cells which are derived from these cell lines. By this, it is to be understood that it is not only the cells as deposited in the CNCM under the indicated references which are covered but also the cells which constitute the progeny of these deposited cells, i.e., on the one hand, those which are obtained by simple multiplication and which may undergo mutations during these multiplications and, on the other hand, those which are obtained after deliberate modification, which are then termed the derived cells, and, of course, also those which have undergone the two types of modification.

Specification, paragraph bridging pages 3 and 4.

Therefore, in light of the specification, instant claims 35 and 37 are not indefinite. Accordingly, Applicants request reconsideration and withdrawal of the rejection under Section 112, second paragraph.

**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview is respectfully requested, with the Examiner and her supervisor, and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

**CONCLUSION**

This application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
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